REMARKS

The Office Action dated January 6, 2010, and the references cited therein, have been considered. Claims 1-8 and 10-26 are presently pending. All claims presently stand rejected.

Applicants have amended the claims to address certain formalities/clarity issues raised in the Office Action. Moreover, the claims have been amended to distinguish the claimed invention, directed to a controlled transverse movement of a sensor during acquisition of signals that are subsequently used to identify strain in tissue which is thereafter related to either hardness or elasticity of the tissue subjected to varying pressure.

Applicants request favorable reconsideration of the grounds for rejection of the previously pending claims in view of Applicants' amendments to the claims and remarks addressing the shortcomings of the prior art with regard to particular recited elements of the claimed invention. Please charge any fee deficiencies to Deposit Account No. 12-1216.

Objection to the Declaration

The Office Action has maintained its **objection to the Declaration** submitted (and accepted) in 2004. This objection has been maintained notwithstanding the previous apparent acceptance of the fully executed (now objected to) declaration in the Office Action mailed on March 16, 2006. Applicants are aware of the requirements of 37 CFR Section 1.52(c)(1), and note that the handwritten changes to the inventor's residence and citizenship **were signed by the inventor** (the handwritten corrections to the citizenship and residence of the inventor were on the originally submitted declaration) on the originally executed declaration (i.e., at the time of signing the original declaration) *on the same sheet of paper* (as required in 37 CFR 1.52(c)(1). Therefore, the requirement to sign changes was met in the original (previously accepted) declaration submission.

Objection to Means Plus Function Elements in Claims 14, 18, and 19

As an initial matter, the original disclosure clearly supports an interpretation of each element in question as being some form of computer/program control element. It would be

impossible for any human to perform any of the functions carried out by the elements in question. It is not believed necessary to amend either the claims or the specification in order to comply with 35 USC section 112, paragraph 6.

"Correlation Detection Means"

The Office Action objects to the term "correlation detection means" in claim 14. In addition to the words of the original claim 14, the "correlation detection means" is described in the specification at least in "correlation detection means 16" in FIG. 1 and the associated written description at page 7, lines 8-12. As those skilled in the art would appreciate from the description, the correlation detection means is carried out by a programmed processor device to compare two consecutive images. When read in conjunction with the description of the (storage) activating means 13 (see, page 7, lines 2-4), the correlation detection means is programmed to gate a control signal that activates storage of image data rendered by the described system.

"First Activating Means"

The Office Action objects to the term "first activating means" in claim 18. In addition to the words of the original claim 18, the "first activating means" is described in the specification at least in "activating means 13" in FIG. 1 and the associated written description at page 7, lines 2-12. As those skilled in the art would appreciate from the description, the activating means 13 is carried out by a programmed processor device to control the storage of received signal data when certain conditions are detected.

"Second Activating Means"

The Office Action objects to the term "second activating means" in claim 19. In addition to the words of the original claim 19, the "second activating means" is described in the specification at least in "activating means 13" in FIG. 1 and the associated written description at page 6, line 19 to page 7, line 2. As those skilled in the art would appreciate from the description, the activating means 13 is carried out by a programmed processor device to control the operation of the actuator (e.g., pullback device) which in turn pulls the imaging sensor through the vessel according to a programmed control scheme (e.g., continuous, stepped, etc.).

Summary of the Rejections

1. Claims 14, 18, 19, 25 and 26 are rejected under 35 U.S.C. §112, paragraph 1 as not being enabled.

2. Claims 14, 18, 19, 25 and 26 are rejected under 35 U.S.C. §112, paragraph 2 as not being enabled.

3. Claims 1-8, 10-12, 13, 14, 18, 19 and 22 are rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter (under Bilski).

4. Claims 1-4, 6-8, 11, 13, 14, 18, and 21-23 are rejected as obvious under 35 U.S.C. §103(a) over Torp et al., US Pat. No. 6,099,471 (Torp) in view of Porat et al., US App. Pub. 2003/0220556 (Porat).

5. Claims 5, 10, 12, 15-17, 19, 20 and 24 are rejected as obvious under 35 U.S.C. §103(a) over Torp in view of Porat and Panescu et al., US Pat. No. 5,848,969 (Panescu).

6. Claims 25 and 26 are rejected as obvious under 35 U.S.C. §103(a) over Torp in view of Porat and Johnson et al., *The Probability Density of Spectral Estimates..., 1999* (Johnson).

Applicants traverse the grounds for each and every rejection for at least the reasons set forth herein below. Applicants address the specific rejections in the order they arise in the Office Action.

1. The Rejection of Claims 14, 18, 19, 25 and 26 as not being enabled

Applicants traverse the rejection of **claim 14** as failing to comply with the enablement requirement. The Office Action states that the specification does not disclose the structure of the "correlation detection means." However, in addition to original claim 14, the original application describes the claimed correlation detection means in a system comprising signal acquisition and signal processing apparatuses. See, FIG. 1. The "correlation detection means" is described in the specification at least in "correlation detection means 16" in FIG. 1 and the associated written description at page 7, lines 8-12. As those skilled in the art would appreciate from the description, the correlation detection means is carried out by a programmed processor to compare two consecutively acquired image data sets. When read in conjunction with the description of the (storage) activating means 13 (see, page 7, lines 2-4), the correlation detection means is programmed to gate a control signal that activates storage of image data rendered by the described system. The Office Action places substantial emphasis on the actual physical structure that carries out the claimed "correlation detection means." However, the Office Action does not state that someone skilled in the art would be unable to practice the claimed invention (e.g., program a general-purpose computer) based upon the disclosure of the original specification.

Applicants traverse the rejection of **claim 18** as failing to comply with the enablement requirement. The Office Action states that the specification does not disclose whether the "first activating means" is carried out by "either a software application or a hardware application." Applicants had no intention to limit their invention to a particular implementation in either application-specific hardware or software executing on a general-purpose processor. Moreover, it is unclear how the subject-matter of claim 18 is not enabled simply because the original specification did not explicitly state whether the function performed by the "first activating means" is carried out by *software* or *hardware*.

Applicants traverse the rejection of **claim 19** as failing to comply with the enablement requirement. The Office Action states that the specification does not disclose whether the "second activating means" is carried out by "either a software application or a hardware application." Applicants had no intention to limit their invention to a particular implementation in either application-specific hardware or software executing on a general-purpose processor. Moreover, it is unclear how the subject-matter of claim 19 is not enabled simply because the

original specification did not explicitly state whether the function performed by the "second activating means" is carried out by *software* or *hardware*.

With regard to the "first" and "second" activating means (distinguished in claims 18 and 19), Applicants original specification (in the Background section) referred to the "first" and "second" activating means as "activating means" and "further activating means." See, page 5, lines 14-16. The two distinct functional components of the first/second activating means are depicted in FIG. 1 by two distinct output lines from the activating means 13 to the actuator 12 and the data storage means 15.

Applicants traverse the rejection of **claims 25 and 26** as failing to comply with the enablement requirement. The Office Action states that the "specification appears to imply every known probability function can be used to perform the task of determining the optimum overlap." Applicants' specification generally describes using a probability function to determine an optimum overlap between consecutive signals so as not to exclude any particular one of a variety of available probability functions. *See, e.g.*, Applicants' application, page 3, line 15 to page 4, line 3. Claims 25 and 26 generally call for using a probability function. The Office Action does not identify any particular probability function that would not work, nor does the Office Action assert that a person skilled in the art would not be able to identify a suitable probability function to carry out the described invention.

The Office Action, at the end of section 10, states that the application fails to disclose "what signals are being used to determine the optimal overlap, and how the optimal overlap is being used to determine hardness of tissue." With regard to the first part of the quote, Applicants note that the signals are signals of a blood vessel wall (acquired using the sensor depicted in FIG. 1). See, page 4, lines 6-8. The comparison is performed between the signal data from consecutive image sets (slices) of an imaged blood vessel wall. With regard to the second part of the quote, Applicants note that the application discloses the optimal overlap determines whether two consecutive signals are sufficiently similar to perform a stress/strain analysis. See, Applicants' application, page 2, line 25 to page 3, line 22.

2. The Rejection of Claims 14, 18, 19, 25 and 26 as being unclear

Applicants traverse the rejection of **claims 14, 18 and 19** as being unclear. The Office Action states that it is unclear whether the "correlation detection means" is carried out by a

software or hardware application. Applicants note that there is no intention on Applicants' part to limit the claimed invention to either special purpose hardware or alternatively a general-purpose processor with application-specific software. The invention can be carried out by a system with either form of programmed control.

Applicants traverse the rejection of **claims 25 and 26** as being unclear. The independent claims describe determining strain of tissue from signals obtained while a sensor is moved while the sensor is moved transversely from a measurement plane. As known from the prior art (described in the background), strain is identified by comparing two image planes to determine the relative changes in form of the cross-sections under differing pressures. The "optimum overlap" relates to the claimed invention with regard to the need to compare two substantially similar consecutive image slices under two different pressures. This aspect of the claimed invention is explained, for example, at page 3, lines 2-22.

3. The Rejection of Claims 1-8,10-12, 13, 14, 18, 19 and 22 as Being Directed To Non-Statutory Subject-Matter

Applicants traverse the rejection of **claims 1-8 and 10-12** as being directed to Non-statutory subject-matter (in view of the Federal Circuit's *Bilski* decision). Applicants note initially that the Supreme Court has relaxed the requirement's for patentability established in the Federal Circuit's *Bilski* decision. The Supreme Court decision requires only that the claimed invention, when viewed as a whole, not be an abstract idea. Applicants note that the present claims would even meet the more restrictive Federal Circuit test under *Bilski*. The presently pending claims at issue recite method steps that could not be performed by a person. No person could carry out the "receiving" step (including sub-steps (a) and (b)). One could not imagine any useful embodiment where a human was left to perform, by hand, the millions of calculations needed to carry out the identifying and relating steps. Moreover, the claimed invention renders a concrete output (hardness or elasticity of tissue value) as a result of the executed steps from the signals received from the sensor.

Applicants traverse the rejection of **claims 13 and 22** in view of the current amendments that are based upon the Office Action's suggestions for overcoming the rejection. Applicants note

that the amendments to claims 13 and 22 do not change the scope of the claims and have been entered with traverse since the originally pending claims 13 and 22 recited patentable subject-matter.

Applicants traverse the rejection of **claims 14, 18 and 19** as being directed to non-patentable subject-matter. The claimed invention is an "apparatus" (see, independent claim 13 from which each depends). Each of the identified claim elements represents a component of a programmed apparatus (see, FIG. 1 which clearly identifies an apparatus including the claimed means plus function elements identified by blocks). In the event the rejection is not withdrawn, Applicants request identification of the *authority* (e.g., Federal Circuit decision) upon which the rejection of claims 14, 18, and 19 is based since Applicants are unaware of any basis for rejecting apparatus claims merely because the apparatus claims include embodiments that execute software to carry out their functionality.

4. Rejection of Claims 1-4, 6-8, 11, 13, 14, 18, and 21-23 as obvious over Torp in view of Porat

Applicants traverse the Office Action's rejection of claims 1-4, 6-8, 11, 13, 14, 18, and 21-23 as obvious over Torp in view of Porat. A *prima facie* showing of obviousness requires identification of each recited element of the claimed invention in the cited combination of references. However, for the reasons stated herein, the combined teachings of Torp and Porat do not disclose each of the recited claim elements in independent claims 1 and 13 (or the rejected dependent claims thereof). In particular, the combined teachings of Torp and Porat neither disclose nor suggest acquiring signals from tissue, that are ultimately used to calculate strain (and thereafter the hardness or elasticity) of the tissue, while the sensor is *controllably* moved in a transverse direction while the sensor receives signals from the tissue. The present amendments to the independent claim 1 are intended to address the point raised in the Office Action that movement of a vessel (due to the heart cycle) would include transverse movement. In response, Applicants have amended claim 1 to recite movement of the sensor under control of an actuator. Applicants note that claim 13 already recites the sensor is controllably moved (and more specifically under control of an actuator in claim 16). There is no teaching in the prior art that consecutive images that are rendered by a sensor that is controllably moved in a transverse

direction while acquiring image signal sets could be used to identify tissue strain (and harness/elasticity).

This controlled withdrawal, as further defined in claims 25 and 26, is performed at a rate to provide optimal overlap of consecutive (image slice) signals. The optimal overlap is determined by a probability function.

For at least the reasons stated herein, independent claims 1 and 13, and each of the pending dependent claims, are patentable over the prior art.

Summary of Applicants' Disclosed/Claimed Invention

Applicants' claimed invention is directed to a method and apparatus for generating hardness/elasticity information of tissue subject to a varying pressure as a sensor is controllably drawn (by an actuator) in a direction transverse to a measuring plane defined by the sensor. The exemplary embodiment discloses a three-dimensional imaging procedure/apparatus wherein an intravascular ultrasound transducer/sensor is withdrawn from a section of a blood vessel, subjected to varying pressure during a cardiac cycle, to render a three-dimensional representation of the hardness/elasticity of the vessel tissue. Moving the sensor during signal acquisition, in the case of a cardiac cycle, has the advantage of minimizing motion of an artery wall in particular circumstances described in Applicants' application at page 9, lines 13-26. In particular, controllably moving (as opposed to the uncontrolled movement referenced in page 9 of the Office Action with regard to Torp's disclosed imaging system) the sensor has the effect of fixing the sensor's position relative to the moving wall of the artery during a period within a cardiac cycle, thereby improving the quality of the palpogram.

Thus, while moving the sensor along a vessel's length, over several signal acquisition cycles, has the overall effect of providing an image of a length of a blood vessel, *in the short term* the movement of the sensor in a transverse direction while acquiring ultrasound signal data within a portion of a cardiac cycle potentially minimizes the effect of an otherwise moving artery wall **(in a transverse direction)** during a single data acquisition period – such artery wall movement arising, for example, from blood pressure/flow variations during a heartbeat cycle.

Applicants' arguments regarding the rejection of claims over Torp in view of Porat

Applicants traverse the previous rejection of claims 1-4, 6-8, 11, 13, 14, 18 and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Torp et al. US Pat. No. 6,099,471 (Torp) in view of Porat et al. US Pub. No. 2003/0220556 (Porat).

Applicants traverse the "grounds for combining" the teachings of Torp and Porat set forth in the first full paragraph at the top of page 11 of the Office Action. The claimed invention is directed to a method (e.g., independent claim 1) and apparatus (e.g., independent claim 13) where consecutive signals are acquired while the sensor is controllably moved in a transverse direction. The Office Action states at page 11 that the combination of Torp and Porat would facilitate determining a tissue parameter *along the length of tissue*. The claimed invention, clarified by the previous and current amendments, is directed to acquiring signal data used to calculate strain while the sensor is controllably moved *as the signals are acquired by the sensor*. The claimed controlled movement of the sensor – while potentially having a confounding effect of providing incomparable signals for purposes of calculating strain – actually has the effect (when properly controlled) of maintaining a substantially "same field of view" for the sensor during the claimed signal acquisition step.

In contrast, the combined teachings of Torp and Porat suggest moving the sensor *when not acquiring signals from the tissue* in order to generate image data along the length of tissue. The movement of the sensor in the cited Porat reference is used to obtain image data for *a new area* of the imaged tissue – resulting in image signals that cannot be used to calculate strain since they are for differing cross-sections of the imaged vessel. The combined teachings of Torp and Porat therefore neither disclose nor suggest Applicants' claimed invention.

The absence of specifically recited claim elements is addressed herein below.

Specific Recited Elements of Independent Claims 1 and 13

Torp does not disclose "relating the strain to at least one of either hardness or elasticity parameters of the tissue" as recited in claim 1. As recited in claim 1 and disclosed in the Application, "generating hardness information of the tissue" is a primary function of Applicants'

invention. *See,* Applicants' specification, page 1, lines 1-4. Moreover, Torp does not disclose a method comprising among other things, "identifying strain of the tissue" as recited in claim 1. Rather Torp discloses a method and apparatus for determining *strain velocity. See* Torp, Abstract. That is, Torp measures the *rate of change in strain*, as distinct from strain. *See* Torp, col.1, ll.30-31. Given the differences between what Torp and Applicants ultimately seek to measure (i.e. strain velocity in Torp versus hardness and elasticity in the Application), Applicants submit that the combined teachings of Torp and Porat do not teach each of the recited elements of independent claims 1 and 13, and therefore the Office Action (notwithstanding its assertion that strain calculation is a by-product of strain velocity) has not established a *prima facie* case of obviousness with regard to Applicants' claimed invention that recites *using strain* (identified from signals acquired by a transversely moving sensor) *to determine hardness or elasticity parameters of the tissue*.

The Office Action asserts that Torp discloses the claimed movement since the sensor will move during the course of the cardiac cycle within the imaged blood vessel. Applicants have amended the claims to distinguish their controlled movement of the sensor during signal acquisition as opposed to Torp's uncontrolled movement identified in the Office Action. Applicants submit that Porat does not disclose a "sensor, where the sensor is moved, *under control of an actuator,* during the receiving signals step: (a) in a direction transverse to the measuring plane, and (b) while the tissue is subject to a varying pressure" (emphasis added) as recited in claim 1.

The Office Action also cites paragraphs [0286] and [0298] of Porat, and suggests Porat discloses a sensor which moves along the tissue in a direction transverse to the measuring plane. However, Porat neither in these paragraphs nor elsewhere in the patent discloses this characteristic (i.e., moving the device, *under control of an actuator, while obtaining measurements*). Porat does not disclose the direction of its sensor's (which Porat patent refers to as "device 200") motion, or specifically whether the sensor's direction of motion is transverse to the measuring plane. Furthermore, Porat does not disclose "the tissue is subject to a varying pressure" during a receiving signals or measuring step. A notable aspect of Applicants' disclosure, and claims, is that the sensor acquires measurement information while the tissue is

subject to a varying pressure, possibly as a result of the natural heartbeat. *See* Applicants' specification, page 9, lines 27 et. seq.

Independent Claim 13 is patentable over Torp and Porat for reasons similar to those discussed for claim 1. Unlike Applicants' claimed invention, Torp does not disclose an "apparatus for generating hardness information of tissue" as recited in claim 13. Rather Torp determines strain velocity using ultrasound. *See* Torp, Abstract. Further, Torp does not "relate the strain to elasticity and/or hardness parameters of a tissue surface." Nor does Torp disclose a "display device for displaying elasticity and/or hardness parameters of the tissue surface." In fact, Torp does not concern elasticity or hardness of tissue whatsoever. Porat, also unlike Applicants' claimed apparatus, does not disclose "a sensor movable through a blood vessel or body cavity for recording signals . . . *while being controllably moved* in a direction transverse to a measuring plane defined by the sensor" as recited in claim 13. Porat does not disclose the sensor's direction of movement, let alone that the sensor moves in a direction transverse to a measuring plane defined by the sensor. Additionally, Porat's sensor is not movable through a blood vessel or body cavity. Paragraphs [0096] and [0298] of Porat indicate that the sensor is placed on the "skin" of the body, preferably close to the "region-of-interest." The sensor is therefore, non-invasive and external to the body, and thus, cannot be movable through a blood vessel or body cavity.

Rejection of Dependent Claims 2-4, 6-8, 11, 14, 18, 21-23

Claims 2-4, 6-8, and 11, which depend upon independent claim 1, are patentable over Torp in view of Porat for at least the reasons set forth above with regard to claim 1. Further, with regard to claim 3, neither Torp nor Porat disclose the "step of displaying elasticity and/or hardness parameters of a tissue surface or tissue volume part."

Claims 14, 18, and 21-23, which depend upon independent claim 13, are patentable over Torp in view of Porat for at least the reasons set forth above with regard to claim 13. Further, with respect to claim 22, Porat does not disclose that its sensor is arranged in a catheter. Fig. 2c of Porat and accompanying descriptions disclose Porat's sensor (device "200" in Fig. 2c of Porat) is not a catheter, since a catheter is a long narrow tube.

5. Rejection of Claims 5, 10, 12, 15-17, 19, 20, and 24 Over Torp in view of Porat and Panescu

Applicants also traverse the continued rejection of claims 5, 10, 12, 15-17, 19, 20, and 24 under 35 U.S.C. 103(a) as being unpatentable over Torp in view of Porat and Panescu. Claims 5, 10, 12, 15-17, 19, 20, and 24 are patentable over Torp in view of Porat, and in further view of Panescu for at least the reasons set forth above with respect to claims 1 and 13 from which these claims depend.

Further, with respect to **claim 12**, Panescu does not disclose that "the tissue is an artery moving during the heartbeat in the longitudinal direction, and the sensor is moved parallel to the longitudinal direction, so that, during at least one detection period, the sensor has a fixed position relative to the wall of the artery." While Panescu's sensor is movable, Panescu does not disclose that the tissue is also moving while the sensor is receiving signals. In addition, Panescu does not disclose that the sensor is moving along a direction parallel to the tissue's direction of motion, such that the sensor has a fixed position relative to the tissue. According to Applicants' disclosure, the elements recited in claim 12 provide improved recording of hardness and/or elasticity properties. *See* Applicants' Application, page 4, lines 13-21, and page 9, lines 23-26.

6. Rejection of Claims 25 and 26 as obvious over Torp in view of Porat and Johnson

Applicants also traverse the rejection of dependent claims 25 and 26. Applicants agree that Johnson does indeed disclose the general concept of calculating probability (density) functions. However, there is no teaching in any of the prior art references to apply such teachings to the claimed method and apparatus recited in claims 1 and 13. In particular, the combined teachings of Torp and Porat suggest the creation of a longitudinal image based upon a series of images taken at points along a vessel. There is no need to have overlapping signals (image slices) since each of Torp's and/or Porat's slices would be an independently generated image slice. In contrast, overlap is needed in the context of Applicants' claimed invention recited in claims 25 and 26 in order to properly calculate strain. Since there is no reason to incorporate Johnson's probability density function into Torp and/or Porat, the claimed invention is not rendered obvious by Torp, Porat and Johnson's combined teachings. **In the event the rejection of claims**

25 and 26 is not withdrawn, Applicants specifically request an explanation of the Office Action's statement (on page 13) that "the ability to determine the optimum overlap of consecutive data…would provide a means of ensuring sufficient overlap of the incoming data to accurately determine the tissue type." Neither Torp nor Porat suggests that the inability to correlate between adjacent data signals prevents accurate determination of their respective output values.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

Mark Joy, Reg. No. 35,562
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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